

# A trial to learn about the long-term safety and efficacy of a study drug (STAR-0215) in adult patients with hereditary angioedema

<b>Submission date</b> 03/01/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/07/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/12/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

STAR-0215-202 is a long-term, open-label trial to assess the safety and efficacy of repeat dosing of STAR-0215 for the prevention of acute attacks in adult patients with Type 1 or Type 2 hereditary angioedema (HAE). Participants may either enroll from the Phase 1b/2 STAR 0215 201 (ALPHA-STAR) trial or be STAR-0215 naïve and not enrolled in STAR-0215-201. HAE is a rare genetic disorder that causes repeated and unpredictable attacks of swelling in the face, arms and legs, abdomen, genitals, and airways. The aim of this study is to assess the long-term safety and tolerability of STAR 0215 in participants with Type 1 or Type 2 HAE. STAR-0215 drug product is supplied as a sterile, preservative-free solution for subcutaneous injection. Participants may receive STAR-0215 subcutaneously for up to 5 years, or until marketing authorization, whichever comes first.

### Who can participate?

About 56 participants with HAE will take part in the trial globally.

### What does the study involve?

All participants will receive STAR-0215 and will be assigned to receive one of three dosing regimens:

Dosing Regimen 1: Day 1 will receive a dose of STAR-0215, then will continue dosing every 3 months

Dosing Regimen 2: Day 1 will receive a dose of STAR-0215, then will continue dosing every 6 months

Dosing Regimen 3: Day 1 will receive a dose of STAR-0215, another dose 1 month later, then will continue dosing every 6 months

The dosing regimen to which they are assigned will depend on the cohort they were in while participating in the STAR-0215-201 trial: If they were in cohorts 1 or 2, they will be in Dosing Regimen 1 and if they were in cohort 3, they will be in Dosing Regimen 2. Participants who never received any dose of STAR-0215 will be assigned to a dosing regimen sequentially in relation to other participants without previous cohort assignment.

Participants will have a total of about 23 study site visits and 4 remote contact visits if in Dosing

Regimen 1, about 17 study site visits and 9 remote contact visits if in Dosing Regimen 2, and about 18 study visits and 9 remote contacts for Dosing Regimen 3. Following the last dose of STAR-0215 they will continue to be monitored to check for any safety concerns, regardless of dosing regimen. This follow-up period consists of 2 study site visits and 4 remote contact visits.

What are the possible benefits and risks of participating?

There may not be a direct medical benefit from receiving the study drug. Participants' HAE may get better, stay the same, or even get worse.

It is possible that the results may not help individuals but the information from this study will help improve treatment for people with HAE in the future.

Where is the study run from?

Astria Therapeutics, Inc. (USA)

When is the study starting and how long is it expected to run for?

May 2023 to March 2031

Who is funding the study?

Astria Therapeutics, Inc. (USA)

Who is the main contact?

Dr Patrick Yong, [patrick.yong@nhs.net](mailto:patrick.yong@nhs.net)

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

1009099

**ClinicalTrials.gov number**

NCT06007677

**Secondary identifying numbers**

STAR-0215-202, IRAS 1009099, CPMS 59129

## Study information

**Scientific Title**

A Phase II long-term open-label trial to assess the safety and efficacy of repeat dosing of STAR-0215 in adult patients with hereditary angioedema (the ALPHA-SOLAR trial)

**Acronym**

The ALPHA-SOLAR Trial

**Study objectives**

1. To assess the long-term safety and tolerability of STAR-0215 in participants with Type 1 or Type 2 hereditary angioedema (HAE)
2. To assess the long-term efficacy of STAR-0215 in participants with Type 1 or Type 2 HAE
3. To characterize the pharmacokinetics (PK) of long-term STAR-0215 dosing in participants with Type 1 or Type 2 HAE
4. To characterize the pharmacodynamics (PD) of long-term STAR-0215 dosing in participants with Type 1 or Type 2 HAE

5. To assess the immunogenicity of STAR-0215 dosed long-term in participants with Type 1 or Type 2 HAE

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 06/03/2024, East Midlands - Leicester South Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8143; Leicestersouth.rec@hra.nhs.uk), ref: 24/EM/0017

Substantial Amendment 01: Approved 05/09/2024

### **Study design**

Interventional non-randomized

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

### **Study setting(s)**

GP practice, Hospital, University/medical school/dental school

### **Study type(s)**

Treatment

### **Participant information sheet**

No participant information sheet available

### **Health condition(s) or problem(s) studied**

Hereditary angioedema (HAE)

### **Interventions**

Current interventions as of 18/12/2024:

In this trial, participants will be assigned to one of the following groups:

#### **Dosing Regimen 1:**

Day 1 participants will receive a dose of STAR-0215, then will continue dosing of STAR- 0215 every 3 months. The maximum duration that participants will receive the study drug is up to 5 years.

#### **Dosing Regimen 2:**

Day 1 participants will receive a dose of STAR-0215, then will continue dosing of STAR- 0215 every 6 months. The maximum duration that participants will receive the study drug is up to 5 years.

**Dosing Regimen 3:**

Day 1 participants will receive a dose of STAR-0215, and another dose one month later. Then participants will continue dosing of STAR-0215 every 6 months. The maximum duration that participants will receive the study drug is up to 5 years.

**Follow-up activity:**

Following the last dose of STAR-0215, participants will continue to be monitored to check for any safety concerns. This period will consist of 4 remote contacts and 2 visits at the study site.

**Previous interventions:**

In this trial, participants will be assigned to one of the following groups:

**Dosing regimen 1:**

Day 1 participants will receive a loading dose of STAR-0215, then will continue dosing of STAR-0215 every 3 months. The maximum duration that participants will receive the study drug is up to 5 years.

**Dosing regimen 2:**

Day 1 participants will receive a dose of STAR-0215, and another loading dose one month later. Then participants will continue dosing of STAR-0215 every 6 months. The maximum duration that participants will receive the study drug is up to 5 years.

**Follow-up activity:**

Following the last dose of STAR-0215, participants will be monitored for 16 months to check for any safety concerns. This period will consist of six remote contacts and two visits to the study site.

**Previous interventions:**

In this trial, participants will be assigned to one of the following groups:

**Dosing regimen 1:**

Day 1 participants will receive a loading dose of STAR-0215, then will continue dosing of STAR-0215 every 3 months. The maximum duration that participants will receive the study drug is up to 5 years.

**Dosing regimen 2:**

Day 1 participants will receive a dose of STAR-0215, and another loading dose one month later. Then participants will continue dosing of STAR-0215 every 6 months. The maximum duration that participants will receive the study drug is up to 5 years.

**Follow-up activity:**

Following the last dose of STAR-0215, participants will be monitored for 16 months to check for any safety concerns. This period will consist of six remote contacts and two visits to the study site.

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

### **Primary outcome measure**

Current primary outcome measure as of 18/12/2024:

Number of participants experiencing treatment-emergent adverse events [time frame: day 1 through study completion, an average of 6 years]

Previous primary outcome measure:

Number of participants experiencing treatment-emergent adverse events [time frame: day 1 through up to 6 years and 4 months]

### **Secondary outcome measures**

1. Change from baseline in monthly HAE attack rate [time frame: day 1, up to 5 years]
2. Severity of HAE attacks experienced by participants [time frame: day 1 through up to 5 years]. All HAE attacks will be classified according to severity (mild, moderate, and severe).
3. Duration of HAE attacks [time frame: day 1 through up to 5 years]. Duration will be reported as shorter than 12 hours, 12 to 24 hours, 24 to 48 hours, and longer than 48 hours.
4. Number of participants experiencing HAE attacks requiring on-demand therapy [time frame: day 1 through up to 5 years]
5. Time to first HAE attack after each dose [time frame: day 1 through up to 5 years]
6. Number of HAE attack-free days [time frame: day 1 through up to 5 years]
7. Number of participants experiencing zero HAE attacks [time frame: day 1 through up to 5 years]
8. Serum concentration of STAR-0215 [time frame: every 3 months for first 2 years, every 6 months for next 3 years]. Blood samples will be collected on dosing days to measure the serum concentration of STAR-0215.
9. Plasma levels of cleaved high-molecular-weight kininogen [time frame: every 3 months for first 2 years, every 6 months for next 3 years]. Blood samples will be collected on dosing days to measure the plasma levels of cleaved high-molecular-weight kininogen (a measure of plasma kallikrein activity).
10. Number of participants with anti-drug antibodies to STAR-0215 [time frame: every 3 months for first 2 years, every 6 months for next 3 years]. Blood samples will be collected on dosing days to assess the formation of STAR-0215 anti-drug antibodies in serum.

### **Overall study start date**

19/05/2023

### **Completion date**

31/03/2031

## **Eligibility**

### **Key inclusion criteria**

Open to participants from STAR-0215-201 (NCT05695248) who have met one of the following conditions:

1. Completed STAR-0215-201 (follow up through 6 months after their last dose)
2. Eligible for STAR-0215-201 and entered the Run-In period but did not qualify for the Treatment Period because they did not meet the criterion for the minimum number of HAE attacks
3. Eligible for STAR-0215-201 and entered the Run-In period but did not complete it for reasons other than not meeting the criterion for the minimum number of HAE attacks (eligibility requires

consultation with the Medical Monitor)

4. Discontinued STAR-0215-201 (for reasons other than safety) after having completed at least 84 days of trial follow-up since their last dose of STAR-0215 (eligibility requires consultation with the Medical Monitor)

Added 19/11/2024:

Open to participants who are STAR-0215 naïve and were not enrolled in STAR-0215-201 (NCT05695248), and have a documented diagnosis of HAE (Type 1 or Type 2).

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

56

**Key exclusion criteria**

1. Any concomitant diagnosis of another form of chronic angioedema, such as acquired C1 inhibitor deficiency, HAE with normal C1-esterase inhibitor protein (also known as HAE Type III), idiopathic angioedema, or angioedema associated with urticaria.
  2. Any exposure to angiotensin-converting enzyme inhibitors or any estrogen-containing medications with systemic absorption (such as hormonal contraceptives or hormone replacement therapy) within 28 days prior to Screening
  3. Any exposure to androgens (for example, stanozolol, danazol, oxandrolone, methyltestosterone, testosterone) within 7 days prior to Screening.
  4. Use of therapies prescribed for the prevention of HAE attacks prior to Screening:
    - 4.1. Lanadelumab within 90 days
    - 4.2. Berotralstat within 21 days
    - 4.3. All other prophylactic therapies, discuss with the Medical Monitor
- Note: Other inclusion and exclusion criteria may apply.

**Date of first enrolment**

26/09/2023

**Date of final enrolment**

31/03/2025

**Locations**

**Countries of recruitment**

Bulgaria

Canada

Czech Republic

England

Germany

Poland

United Kingdom

United States of America

**Study participating centre**

**St James' University Hospital**

Leeds Teaching Hospitals NHS Trust

Beckett Street

Leeds

United Kingdom

LS9 7TF

**Study participating centre**

**Addenbrookes Hospital**

Cambridge University Hospitals NHS Foundation Trust

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## **Sponsor information**

**Organisation**

Astria Therapeutics, Inc. (USA)

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**Sponsor type**

Industry

**Website**



## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Astria Therapeutics, Inc.

## **Results and Publications**

### **Publication and dissemination plan**

1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Other publication
6. Submission to regulatory authorities

Coded study data will be shared via secure Sponsor systems. Data sharing will be in accordance with current data privacy legislation and restricted to authorized parties with the necessary confidentiality agreements in place.

### **Intention to publish date**

31/03/2032

### **Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

### **IPD sharing plan summary**

Data sharing statement to be made available at a later date